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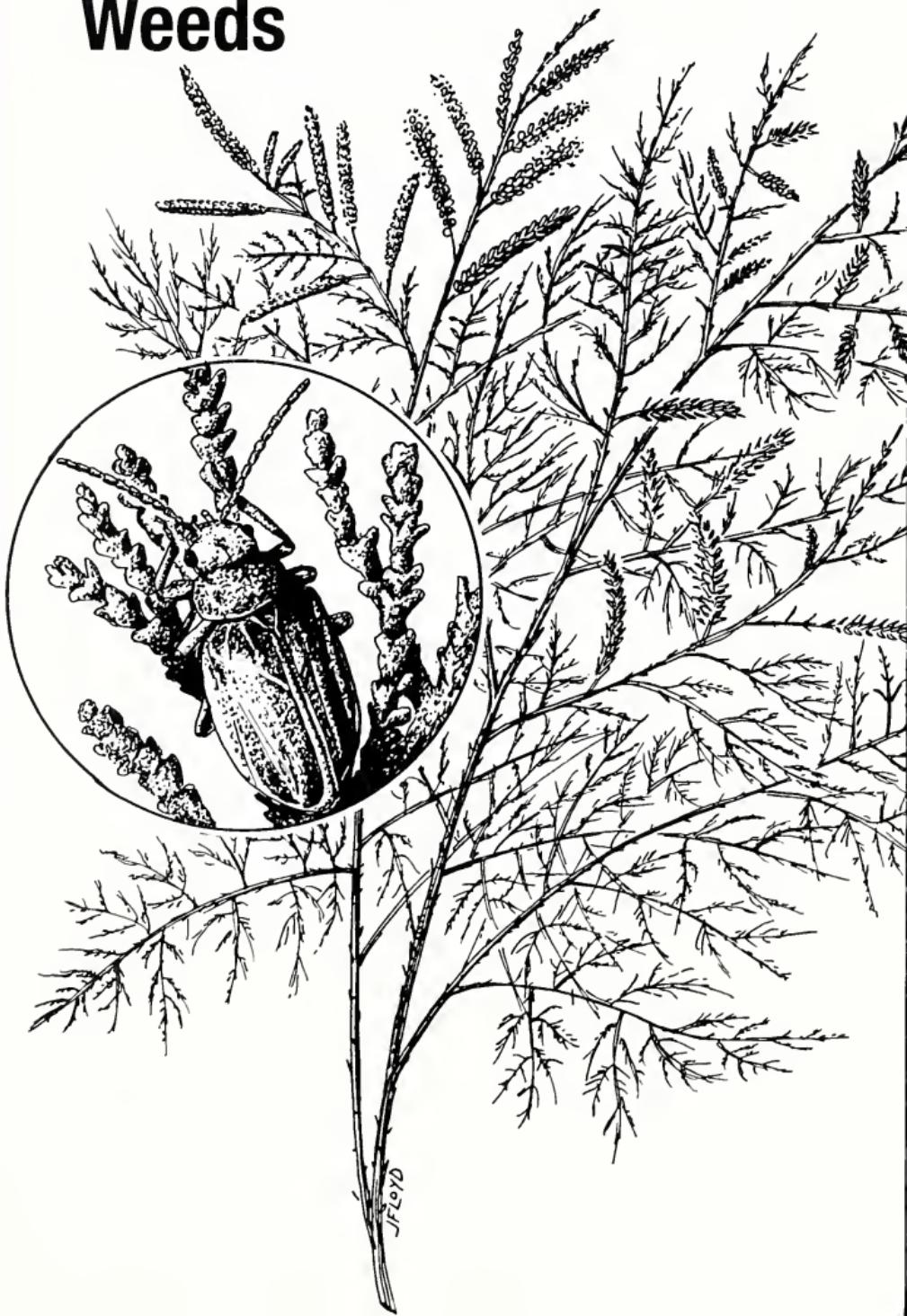
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The Approval Process for Environmental Release of Biological Control Agents of Weeds





The Plant Protection Act of 2000 provides the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) with the authority to regulate "any enemy, antagonist or competitor used to control a plant pest or noxious weed." However, authorities such as the National Environmental Policy Act (NEPA) and the Endangered Species Act (ESA) will affect the decision to release a nonindigenous weed biocontrol agent into the environment. The approval process can be very complicated and difficult to navigate without guidance.

The purpose of this brochure is to provide an overview of the weed biocontrol approval process and to help weed biocontrol researchers navigate the approval process as efficiently as possible. APHIS' Plant Protection and Quarantine (PPQ) permit unit wants to

- Encourage early communication with all Federal and State agencies involved in the approval process.
- Facilitate proper compliance with applicable environmental regulations.
- Promote input from reviewers to address problems at an early stage.
- Provide guidelines for preparation of environmental compliance documents.
- Prevent costly and time-consuming delays resulting from lack of early communication with regulatory agencies and other reviewers.
- Enhance transparency and consistency in the process.

Process Steps

Contact the Technical Advisory Group for Biological Control Agents of Weeds

Whether or not a candidate biological control agent has been identified, we strongly recommend that applicants submit a proposed test plant list to the Technical Advisory Group (TAG) for Biological Control Agents of Weeds. This interagency group was established to advise weed biocontrol researchers and provide the PPQ permit unit with a recommendation on the proposed action. At this early stage of the approval process, the TAG will make recommendations on the target weed choice and comment on the proposed test plant list for host specificity testing. For more information about the TAG and details on submitting a TAG petition, see the TAG Web page at <http://www.aphis.usda.gov/ppq/permits/tag>.

Contact the Departments of the Interior and Commerce

In addition to submitting a TAG petition, we recommend that applicants contact the Department of the Interior to be sure that threatened and endangered species are considered in the test plant list. The appropriate agency is usually the U.S. Fish and Wildlife Service (FWS). But sometimes the National Marine Fisheries Service (NMFS), within the Department of Commerce, must be consulted, depending on the nature of the proposed action. Both these agencies have responsibility for enforcing the ESA. Although an FWS representative participates on the TAG, this does not substitute for the ESA consultation process. Separate and direct contact with these agencies will facilitate the consultation process. Visit the FWS' Endangered Species Contacts Web page at <http://endangered.fws.gov/contacts.html> to find the location of its nearest regional office.

Receiving input on a weed biocontrol project at an early stage from the TAG and Departments of the Interior and Commerce can disclose problems or concerns that permit applicants can address at an early stage, potentially saving years of delays.

Importation of Potential Organisms Into the United States

To import a potential weed biocontrol organism into the United States for host specificity testing, you must submit a permit application (PPQ Form 526) to PPQ. Download this form from the PPQ Web site at

<http://www.aphis.usda.gov/ppq/permits/weedbio.htm>. It takes 4 to 6 weeks from submission of the application to receive a permit. Approved biocontrol agents can be imported only into an adequate high-security containment facility in the United States.

Begin Preparation of Draft Environmental Documents

Issuance of permits by PPQ for the release of nonindigenous weed biocontrol organisms is considered a Federal action and triggers compliance with the NEPA and the ESA. Although PPQ is ultimately responsible for compliance with those environmental statutes, the applicant can lessen the turnaround time by preparing draft documents for PPQ to finalize.

The document required for NEPA compliance is the Environmental Assessment (EA), a concise public document that provides sufficient evidence and analysis to determine if a finding of no significant impact (FONSI) can be reached or if an environmental impact statement (EIS) must be prepared. The EA provides the public with the potential positive and negative environmental impacts that may occur as a result of the release of a nonindigenous biocontrol organism into the environment.

The document required for compliance with the ESA is the Biological Assessment (BA). This document is usually submitted to the FWS. The BA should include several elements: (1) a description of the action to be considered; (2) a description of the specific area that may be affected by the action; (3) a description of any listed species or critical habitat that may be affected by the action; (4) a description of the manner in which the action may affect any listed species or critical habitat and an analysis of any cumulative effects; (5) relevant reports, including any EIS or EA; and (6) any other relevant available information on the action, the affected listed species, or critical habitat.

For more information about preparation of EAs and BAs contact APHIS Environmental Services at (301) 734-4844 or visit its Web site at <http://www.aphis.usda.gov/ppd/es/index.html>. For examples of EAs and BAs visit the PPQ weed biocontrol Web site at <http://www.aphis.usda.gov/ppq/permits/weedbio.htm>.

Note: Federal agencies must also consider their own NEPA implementing procedures specific to any proposed actions.

Submit Release Petition to the TAG

After host specificity testing is completed, a petition for release of the biocontrol agent must be submitted to the TAG for recommendation. All proposed first-time releases of nonindigenous weed biocontrol agents must be reviewed and recommended by the TAG. See the TAG manual or TAG Web page for the suggested format for release petitions.

Submit Permit Application Requesting Environmental Release, Draft EA, and Draft BA to APHIS

When you receive a recommendation from the TAG for the release of the weed biocontrol organism, you must submit an application (PPQ Form 526) requesting release of the biocontrol agent to PPQ along with the draft EA and BA. To speed the review process, it is important to submit documents as close to complete as possible.

Consultation With FWS

According to the ESA, any action that is authorized, funded, or carried out by a Federal agency must comply with the consultation requirements of section 7 of the ESA. This compliance may be achieved through formal or informal consultation. Although applicants should have been in contact with FWS or NMFS from the beginning of the process, PPQ determines if formal consultation with those agencies must be conducted at this point in the process. Informal consultation involves the submission of the BA to FWS and/or NMFS for concurrence with a determination that the release of the biocontrol organism "is not likely to adversely affect endangered or threatened species or their habitats." Formal consultation is required when there are concerns that the proposed release may adversely affect endangered or threatened species or designated critical habitat. For weed biocontrol releases, both formal and informal consultations are conducted between FWS and/or

NMFS and APHIS. However, applicants from Federal agencies are strongly encouraged to conduct their own consultations. Non-Federal applicants may conduct informal consultations but first must be designated as a non-Federal representative by PPQ. In any case, early, open communication between the applicant, PPQ, FWS, and NMFS is essential in order to ensure efficient movement through this portion of the approval process. For more information about section 7 consultation, contact APHIS Environmental Services.

Finalization of the EA, Public Comment, Final Decision

Once the section 7 consultation is complete, PPQ incorporates the response from FWS and/or NMFS (either Letter of Concurrence or Biological Opinion) into the EA and makes any final changes necessary. The USDA Office of the General Counsel (OGC) reviews the EA to be sure it meets all legal standards. Once the EA has been approved by OGC, PPQ publishes a 30-day notice of availability of the EA in the *Federal Register* to allow the public to comment on the proposed action. After considering the comments, PPQ either reaches a FONSI (the desired outcome) and issues the release permit, advises the applicant that an EIS must be prepared (a document prepared in compliance with NEPA when significant impacts are expected from the proposed action), or advises the applicant to discontinue the project.

For More Information

For more information about the approval process for weed bio-control organisms, visit the PPQ biocontrol Web site at <http://www.aphis.usda.gov/ppq/permits/weedbio.htm> or call the APHIS PPQ Permits and Risk Assessment staff at (301) 734-8758.

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